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510(k) Summary
(As required by 21 CFR 807.92(a))

OCT 22 2008

A. Submitter Information

BMDI Pty Ltd.
63-79 Parramatta Road
Suite 306
Silverwater, Australia NSW 2128

Phone Number: 949-433-3058
Fax Number: 949481-5745
Contact: Jim Barley
US Agent

Trade Name: InviroStripe Standard 3, 5 and 10 ml hypodermic syringes

B. Device Information

Trade/Proprietary Name:	InviroStripe Standard 3, 5 and 10 ml hypodermic syringes
Common name of device:	Piston Syringe
Classification Name:	Piston Syringe
Product Code:	80 FMF
Regulatory Class:	II
Classification Number:	880.5860
Reason for 510(k):	New Device

C. Predicate Device: Yi Xin Sterile Syringe for Single Use

Predicate 510(k) #: K050999

Predicate product code: FMF

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D. Device Description

The InviroStripe Standard 3, 5 and 10 ml hypodermic syringes are used to inject medicines and vaccines into, or withdraw fluids from, the body.

The piston syringe is a plastic disposable htpodermic syringe made of the following components:

1 Barrel – The barrel has a scale showing the capacity of the syringe. In addition, the tip of the barrel has a luer lock fitting for the user to attach a needle.
2 Plunger – The plunger is used to aspirate and inject fluids into and out of the syringe.
3 Stopper – The Stopper maintains the fluid in the barrel between the syringe nozzle and the Plunger.
4 Cannula – The cannula/needle penetrates the patient's skin to inject/withdraw fluid from the body.
5 Cap – Covers the cannula/needle until the syringe is to be used.

The InviroStripe Standard 3, 5 and 10 ml hypodermic syringes are sterilized by Ethylene Oxide Gas and supplied sterile in a tray pack. Twenty five syringes without needles are packaged in a tray and sealed with a tyvek Lid. Each tray pack and case is labeled with the contents and the appropriate information per the FDA's Quality System Regulation and Labeling requirements.

E. Statement of Indications for Use

The InviroStripe Standard 3, 5 and 10 ml hypodermic syringes are used to inject medicine or vaccines into, or withdraw fluids from, the body.

F. Comparison of Required Technological Characteristics:

Information was submitted to demonstrate that there are no significant differences in technological characteristics between the InviroStripe Standard 3, 5 and 10 ml hypodermic syringes and the cited predicate device.

G. Summary and Conclusion of Nonclinical and Clinical Tests:

The intended use of the InviroStripe Standard 3, 5 and 10 ml hypodermic syringes are identical to that of the cited predicate device. Any differences in technological characteristics were insignificant and do not raise new issues of safety or effectiveness.

Performance testing consisted of compliance to the applicable sections of the following voluntary standards:

1. ISO 594-1:1986, "Syringe, Syringe Needle and Other Medical Apparatus 6% (Lu-Er) Taper Connector – Part One: General Requirement"
2. ISO 594-2:1986, "Syringe, Syringe Needle and Other Medical Apparatus 6% (Lu-Er) Taper Connector – Part Two: Locked Connector"
3. ISO 7886-1:1993, "Single Use Sterile Syringe"
4. ANSI/AAMI/ISO 11135 - "Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization
5. ISO 11607;2003 – Packaging for terminally sterilized medical devices
6. ISO 10993-4:2006 – Biological evaluation of medical devices Part 4: Selection of tests for interactions with blood

Conclusion:

The InviroStripe Standard 3, 5 and 10 ml hypodermic syringes are substantially equivalent to the Yi Xin Sterile Syringe for Single Use in indications for use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

BMDI Pty Limited
C/O Mr. James Barley
James Barley
33572 Sea Wind Court
Dana Point, California 92629

OCT 22 2008

Re: K081436
Trade/Device Name: InviroStripe 3,5 and 10 ml Luer Lock Syringes
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: October 1, 2008
Received: October 6, 2008

Dear Mr. Barley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indication For Use

510(k) Number (if known): K081436

Device Name: InviroStripe 3, 5 and 10 ml Luer Lock Syringes

Indication For Use:

The InviroStripe 3, 5 and 10 ml Standard Luer Lock Syringes are used to inject medicines into, or withdraw fluids from the body.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) And/Or Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for ADW

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081436